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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,576	DELANEY ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 13-19* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/04 & 07/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-5, 13-18) in the reply filed on 01/29/09 is acknowledged

Claims 19is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II (claim 19), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/29/09.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "the system comprises both said partial and total occlusion catheter inserts" of claim 14 and the limitation "at least one of said elements a, b, c further comprises a separate guide wire lumen" of claim 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 14 and 15 are mis-descriptive.

In claim 14, according to Figs. 1-4, either a total occlusion catheter comprising an elongated tube having an open end or a partial occlusion catheter insert comprising an elongated tube having a sealed distal end 48. But there are no Figures show the limitation "the system comprises both said partial and total occlusion catheter inserts" as in claim 14. Based on claims 13-14 of Applicant, it must have four catheters in the system. For example: first catheter is aspiration catheter 22; second catheter is a second elongated tube coaxially positioned inside of the aspiration catheter; third catheter is total occlusion catheter; and fourth catheter is partial occlusion catheter. Meanwhile, Fig. 4 only shows three catheters in the system.

In claim 15, based on claims 13 and 15, there is no figs show that the guide wire lumen having separate lumen in the system.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Zadno-Azizi et al. (US 6,022,336).

Zadno-Azizi discloses a catheter device comprising: first, second and third lumens 32, 30 and 24; wherein at least one of the lumens is fabricated from a material sufficient for delivery of an acidic dissolution solution (col. 14, lines 27-37); a first vascular occlusion means 26, 28. The first, second and third lumens are coaxial and movable.

Applicant acknowledges that the materials fabricated include: biocompatible polymers, e.g., polyimide, PEBAX, polyethylene, and the like (pg 6 of Specification). These materials are similar as Zadno-Azizi discloses in col. 14, lines 27-37).

Claims 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Simpson et al. (US 5,462,529).

Simpson discloses a catheter device comprising: an aspiration catheter 110comprising an elongated tube having an aspiration lumen 126 ending in an open distal end and an inflatable balloon 114 at the distal end; and a second elongated tube 118 coaxially positioned inside of the aspiration catheter 126; and at least one of:

a total occlusion catheter 112 inserted comprising an elongated tube having an open distal end 154 (Fig. 10); or

a partial occlusion catheter 112 insert comprising an elongated tube having a sealed a distal end 134, and inflatable balloon 116 at the distal end of the elongated tube; at least one infusion port 148 proximal to said inflation balloon; wherein at least the partial occlusion catheter inserts are capable of being slidably positioned within the second elongated tube to produce an annular space at the distal end of the elongated tube through which fluid may flow.

Regarding claim 15, the separate guide wire lumen 138 is provided in the system.

Regarding claims 17-18, the second elongated tubular member is capable of flowing in the fluid communication with buffer solution source or the catheter inserts are capable of fluid communication with an acidic solution source.

Claims 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Clement et al. (US 5,681,336).

Clement discloses a catheter device comprising: an aspiration catheter 24 comprising an elongated tube having an aspiration lumen 49 ending in an open distal end and an inflatable balloon 26 at the distal end; and a second elongated tube 46 coaxially positioned inside of the aspiration catheter 24; and at least one of a partial occlusion catheter insert comprising an elongated tube 18 having a sealed a distal end, and inflatable balloon 47 at the distal end of the elongated tube 18; at least one infusion port 57 proximal to said inflation balloon; wherein at least the partial occlusion catheter inserts are capable of being slidably positioned within the second elongated tube to produce an annular space at the distal end of the elongated tube through which fluid may flow.

Regarding claim 15, the separate guide wire lumen 10 is provided in the system.

Regarding claims 17-18, the second elongated tubular member is capable of flowing in the fluid communication with buffer solution source or the catheter inserts are capable of fluid communication with an acidic solution source.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement or Simpson.

Clement or Simpson discloses the invention substantially as claimed. Clement or Simpson does not further disclose an occlusion catheter in the system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adding another catheter in the system since it was known in the art that providing plurality of catheter for delivery different agent in the system as for intended use.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 13-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent Nos. 6,290,689; claims 1-24 of U.S. Patent Nos. 6,533,767; claims 1-13 of U.S. Patent Nos. 6,730,063; claims 1-27 of U.S. Patent Nos. 7,141,045; claims 1-51 of U.S. PG Pub 2003/0104073; claims 1-32 of U.S. PG Pub 2003/0199820; claims 1-19 of U.S. PG Pub 2005/0059955; claims 1-24 of U.S. PG Pub 2006/0161103; claims 1-51 of U.S. PG Pub 2007/0173784.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device and method of instant claims are fully disclosed and covered by the claims in the patents and the copending application claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763